ACGT
Advancing Clinico Genomic Trials on Cancer

Requirements for european multicentre trials including genetic data of subjects

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Berlin, December 8th, 2006

http://www.eu-acgt.org

Information Society and Media

The ACGT project (FP6-2005-IST-026996) is funded by the European Commission Information Society and Media DG under the 6th Framework Programme.

ACGT

- Advancing Clinico Genomic Trials in Cancer
- Integrated Project
- EU-Funding: ~11.9 Mio €
- 25 Partners
- PM: FORTH (Greece) and ERCIM (France)

Outlook and Challenges

- Explosion of knowledge about cancer as a disease process
- Beginning to understand cancer at the molecular level.
- Translation of molecular medicine into personalized care

Challenges

- To universally integrate personalized medicine into cancer prevention, diagnosis and treatment, researchers and clinicians must
  - be able to gain rapid access to multiple types of specific information about an individual patient.
  - information to which they do not currently have easy access.

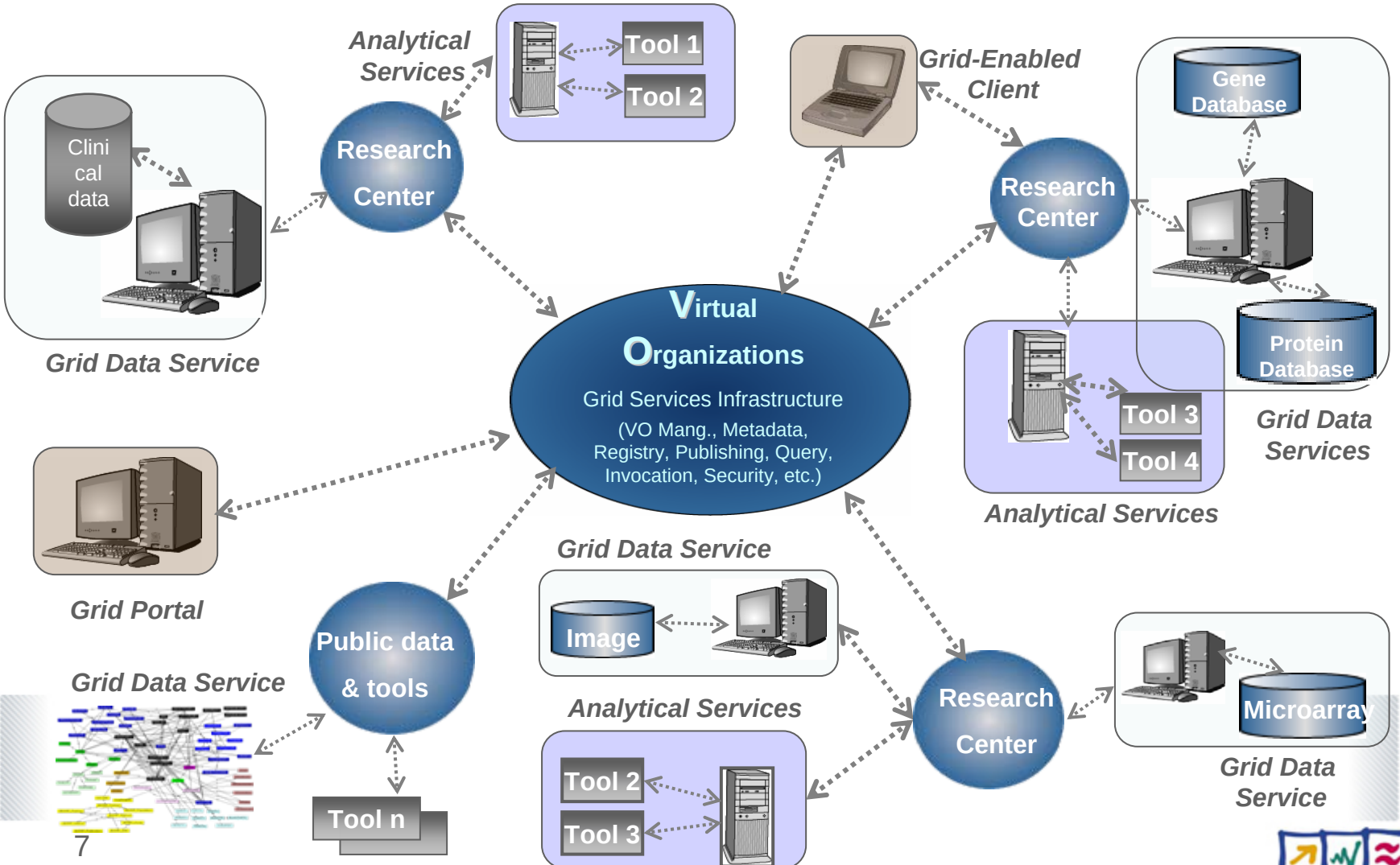
The ACGT Vision

- Connectivity and interoperability of cancer research on a molecular level
- by developing a semantic grid services infrastructure in support of multi-centric, post-genomic clinical trials and, thus,
- by enabling for discoveries in the laboratory to be quickly transferred to the clinical management and treatment of patients.

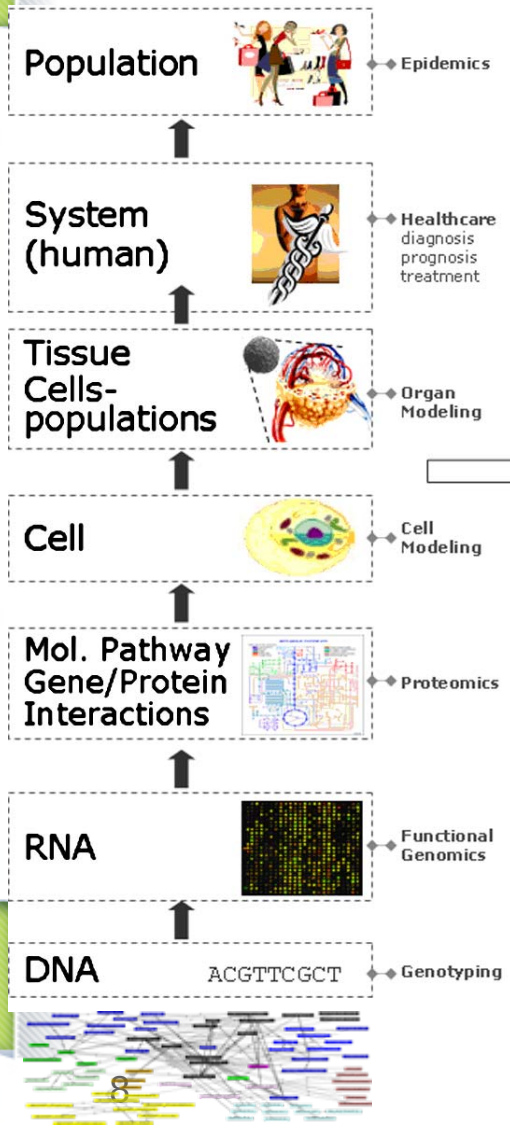
The ACGT objectives

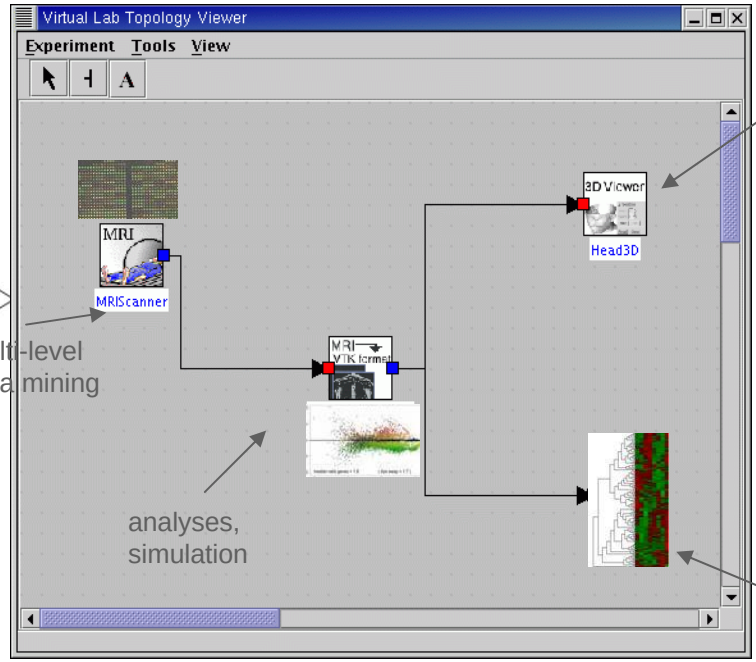
- The ultimate objective of the ACGT project is the provision of a unified technological infrastructure (a Problem Solving Environment – PSE) which will facilitate:
  - the seamless and secure access to heterogeneous, distributed CT databases as well as public biomedical databases;
  - by providing a range of tools for
    - the analysis of such integrated, multilevel clinico-genomic data;
    - the visualization of analytical results;
  - in the context of discovery-driven analytical workflows;

The ACGT Vision & VOs

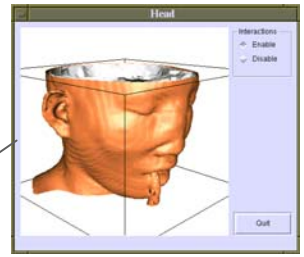


A Problem Solving Environment

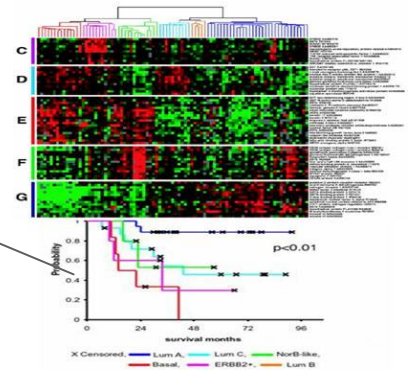




ACGT experiment topology



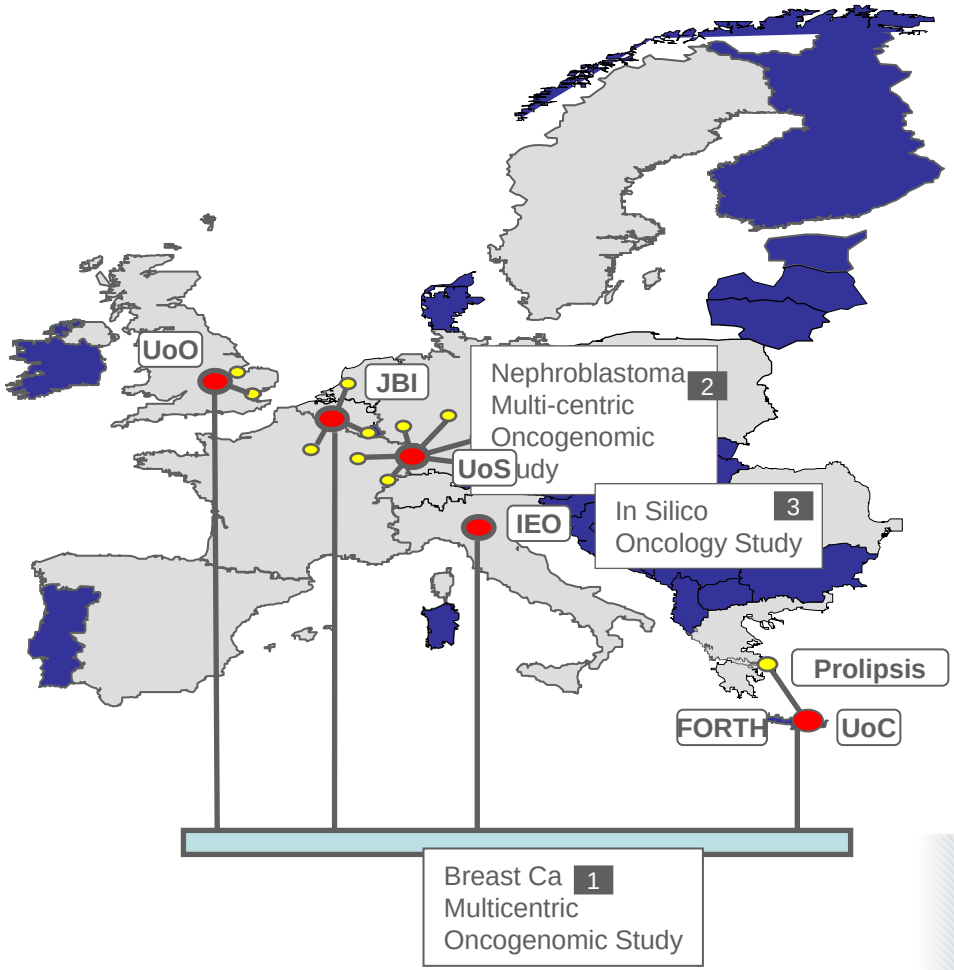
2D/3D visualization for in silico models



Microarray data processing for molecular classification of disease

Our approach: The ACGT CTs

- Multicentric TOP trial – Breast Cancer
- SIOP 2002 – paediatric nephroblastoma
- In Silico modeling and simulation of tumor growth & response to treatment



WP 10: Legal and ethical issues

- **IRI** (Hannover/Germany, lead)
- **CRID** (Centre de Recherches Informatique et Droit, [Namur/Belgium])
- **FSP BIOGUM** (Forschungsschwerpunkt Biotechnik, Gesellschaft und Umwelt [Hamburg/Germany])
- **University Hospital of the Saarland**, Paediatric Haematology and Oncology (Saarland/Germany)
- **Jules Bordet Institute** - Department of Medical Oncology (Brussels/Belgium)

Relationship law – ethics - security:

Ethics: justification of what is right

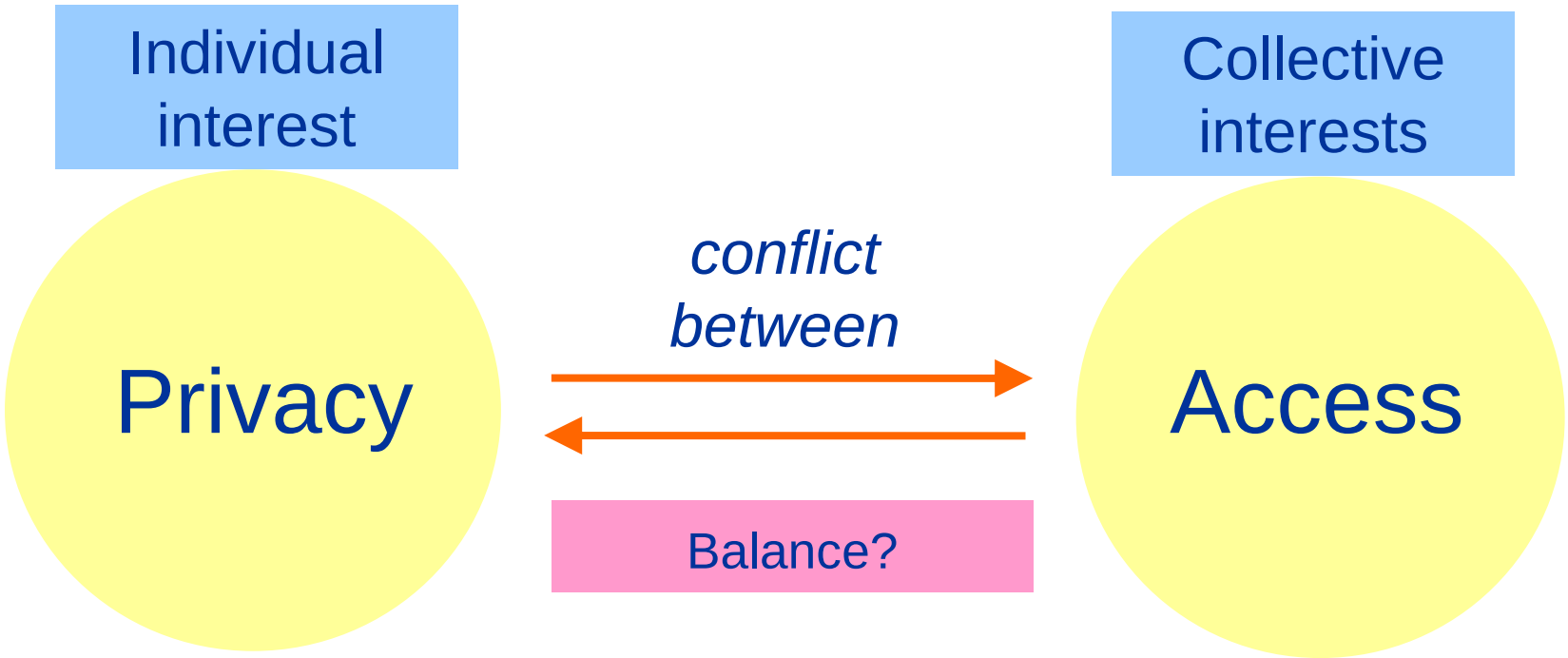
Law: codification of what is right

Security: Technical implementation of ethical and legal requirements

Ethical and legal concerns

- **Complexity** of networked ICT systems: security, confidentiality, transperancy?
  - **Data protection?**
  - **Data security?**
  - **Informed consent?**
  - **Access?**
  - Liability?
  - Standards?

Value conflicts



Ethical considerations

- In addition to existing legal regulations, ethical principles may be used to address these value conflicts, namely:
  - Human dignity
  - Autonomy
  - Beneficence and non-maleficence
  - Justice
  - Solidarity
  - ……

Basic principle: Autonomy

Autonomy needs Consent

Is an informed consent always needed?

- Pro arguments
  - Guarantees autonomy and self determination
  - Is element of a fundamental right
  - Protects the individual in the best possible way
- Contra arguments
  - Technically difficult
  - Not always achievable
  - Makes research expensive
  - Might become obsolete
  - Not always needed by law
  - Not always sufficient

→Law has to find a balance between public and private interests

→Law uses the concept of **personal** data to balance these interests

Data protection regarding human genetic research

Art. 2 Dir. 95/46/EC

'Personal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); **an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number** or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity

Data protection regarding human genetic research

Recital 26 Dir. 95/46/EC

Whereas the **principles of protection** must **apply** to any information concerning an identified or identifiable person; whereas, to determine whether a person is identifiable, account should be taken of all the means likely reasonably to be used **either by the controller or by any other person** to identify the said person; whereas the principles of protection shall **not apply** to data **rendered anonymous** in such a way that the data subject is no longer identifiable;

...

Data protection regarding human genetic research

- Three key issues

Data protection regarding human genetic research

1. Genetic data always personal data?
2. Can pseudonymous genetic data be regarded as anonymous data for a controller, who doesn‘t have the link?
3. How to define additional knowledge, by which a person can be identified?

Genetic data = personal data?

- Genetic data is **potentially** personal data, as the identification of the data subject is always possible if the controller has additional knowledge (for example reference templates).

- Condition for anonymization of genetic data: De facto anonymous data = anonymous data

  → **Relevant factor: effort for identification**

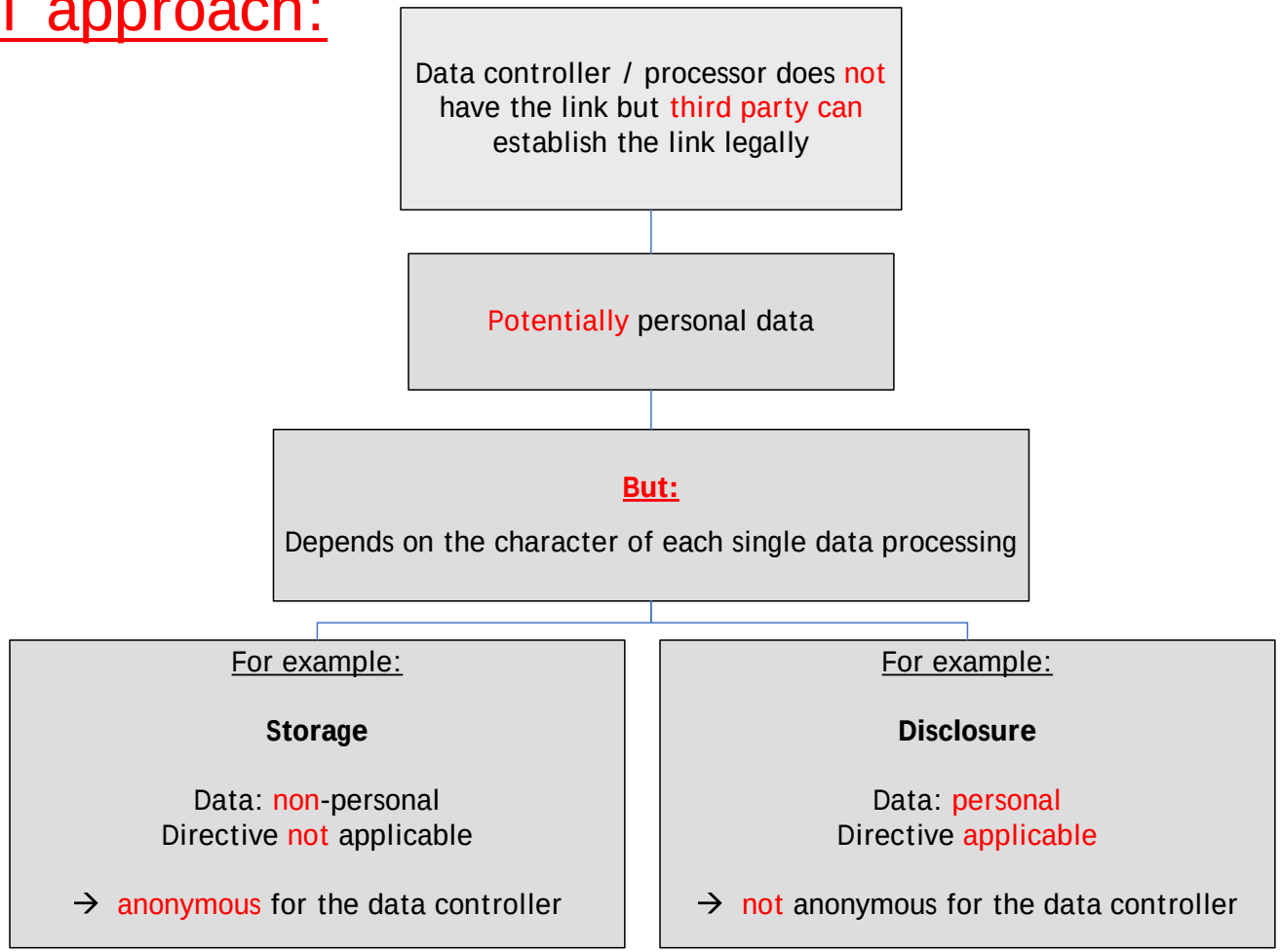
Pseudonymous = de-facto anonymous?

- Same situation for the data controller
- Missing link → de-facto anonymous data

→ What does missing link mean?

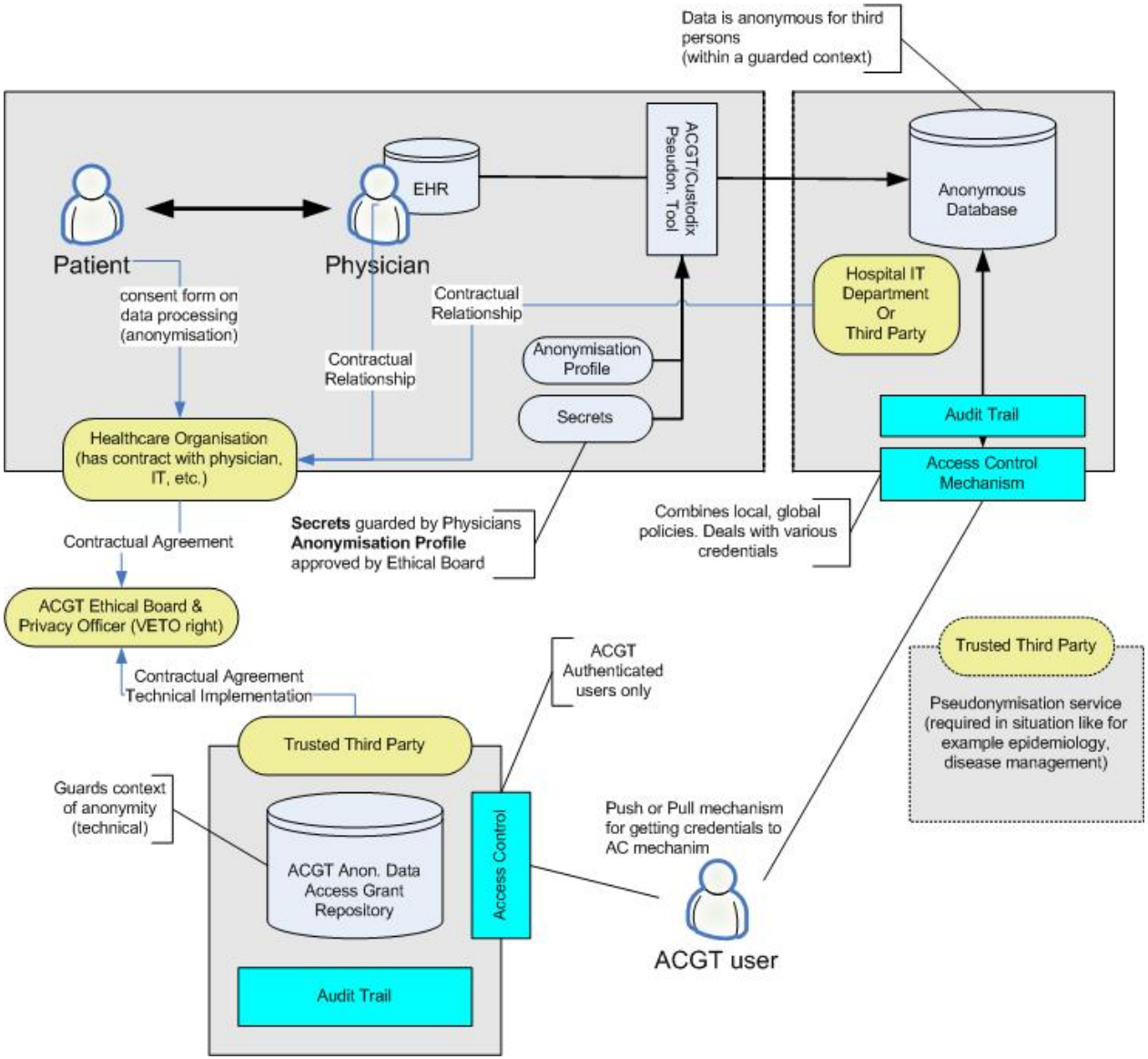
Relation between the quality of data and additional knowledge/information

- ACGT approach:



Conclusion

- A legal basis conform with data protection rules is needed, whenever the data processing contains the risk of deanonymization of the data
- This legal basis has to be enforced by security measurements


Data is anonymous for third persons
(within a guarded context)
Patient
EHR
Physician
ACGT/Custodix Pseudon. Tool
Anonymous Database
consent form on data processing (anonymisation)
Contractual Relationship
Contractual Relationship
Hospital IT Department Or Third Party
Anonymisation Profile
Secrets
Audit Trail
Access Control Mechanism
Healthcare Organisation (has contract with physician, IT, etc.)
Secrets guarded by Physicians
Anonymisation Profile
approved by Ethical Board
Combines local, global policies. Deals with various credentials
Contractual Agreement
ACGT Ethical Board & Privacy Officer (VETO right)
Contractual Agreement
Technical Implementation
ACGT Authenticated users only
Trusted Third Party
Pseudonymisation service (required in situation like for example epidemiology, disease management)
Trusted Third Party
Guards context of anonymity (technical)
ACGT Anon. Data Access Grant Repository
Access Control
Push or Pull mechanism for getting credentials to AC mechanim
ACGT user
Audit Trail

Thank You!

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